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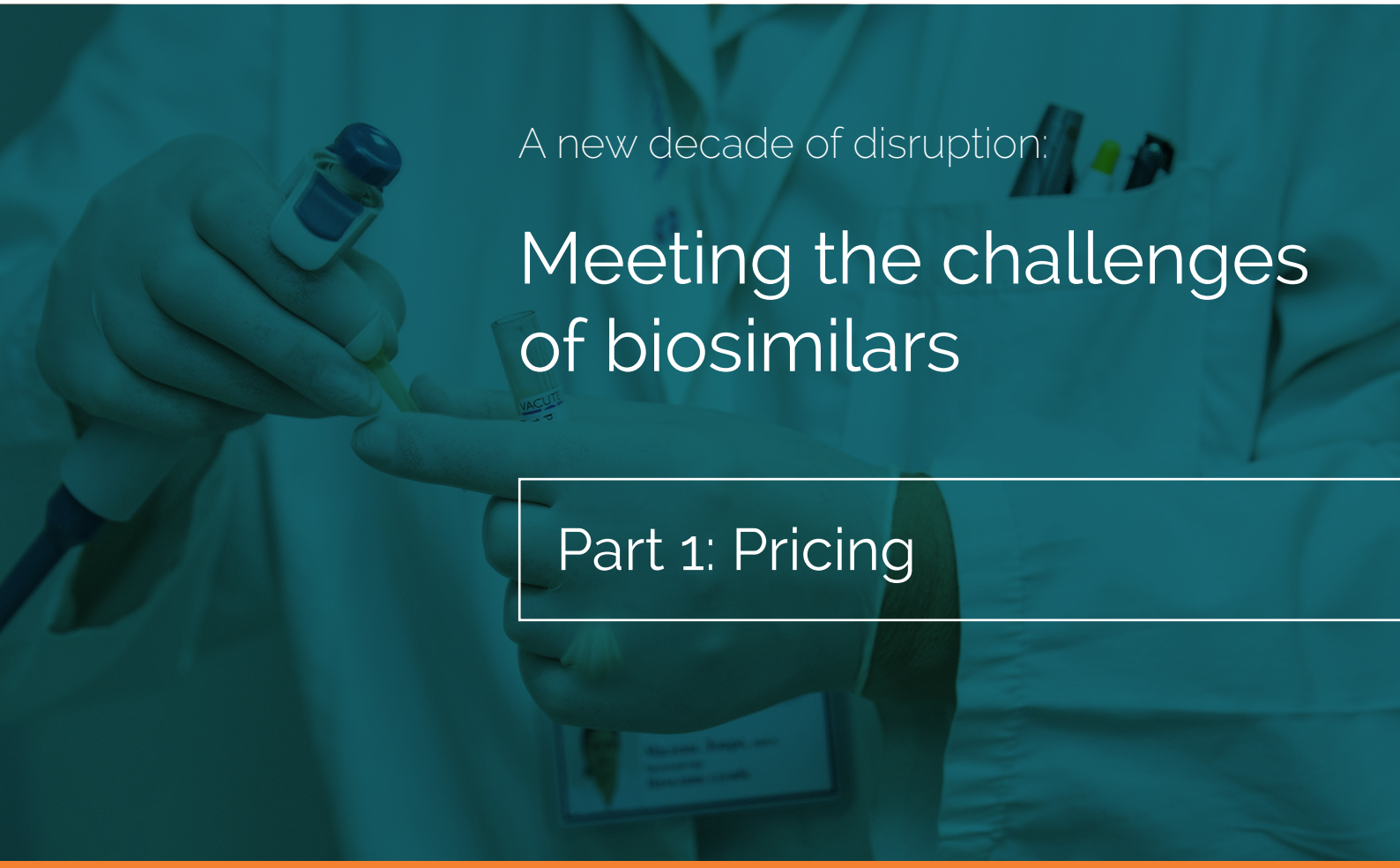

A new decade of disruption:

Meeting the challenges of biosimilars

Part 1: Pricing

What price has success?

Addressing critical needs in chronic diseases but costing payers and patients dear, biologic medicines face their biggest hit yet from a wave of new MAb biosimilars. With high hopes for health system savings yet clear signs that price is not the only driver of usage, the search is on to find the winning hand. The question is what will it take to stay competitive in this growing market?

Following our introduction article, this brief is the first of SKIM's trilogy of biosimilar briefs, in which we address three key questions in developing successful strategies for biologics manufacturers:

1. What price has success?

2. Who's influencing who?

3. What's driving physician behavior?

A price discount: exception or direction?

In 2015, global spending on biologic medicines reached a record $154bn.[1] With prices averaging 22 times those of small molecule brands,[2] it is projected to reach $390bn by 2020, with biologics accounting for around 28% by value of the total pharmaceutical market.[3] Much of the growth is being driven by monoclonal antibodies (MAbs), which typically cost between $10,000 and $100,000 annually.[4] In some cases, more. Topping $400,000 per year, Soliris (eculizumab) is one of the most expensive drugs available globally.[5]

However, payers have been pushing back, applying measures that control the use of biologics. In the USA, increasing barriers include prior-authorization, higher patient cost-sharing, specialty tier placement, step-therapy requirements, and even blocks on co-pay assistance programs for non-preferred products.[6,7] In Europe, the high cost of biologic disease modifying anti-rheumatic drugs (DMARDs) such as Humira (adalimumab), Enbrel (etanercept) and Remicade (infliximab) has been found to severely restrict access for about 40% of the population.[8] In the UK, hefty price tags have seen a string of rejections by NICE, with cancer MAbs Avastin (bevacizumab), Kadcyla (ado-trastuzumab emtansine) and Perjeta (pertuzumab) among the casualties. Now, in addition to their greater scrutiny of high prices and cost-effectiveness, payers are also making strategic use of the growing availability of biosimilars.

It has been estimated that with a rich pipeline, including many candidates targeting impending loss of exclusivity on a number of market leading MAbs, biosimilars offer the potential to yield savings of up to $110bn in Europe and the USA through 2020.[9] Good news for health systems under pressure to curb escalating cost growth, but for biologics manufacturers this marks a new maelstrom in an increasingly challenging market.

Predicated on lower prices, the biosimilars opportunity in Europe over the last 10 years has seen discounts (in some countries, mandatory) averaging around 30%.[10] Similar levels have been anticipated going forward, both here and in the USA.[11] However, indications from entry of the first MAb biosimilars suggest a more aggressively competitive pricing landscape, with unexpectedly high discounts of around 70% for infliximab in Norway, Denmark and Finland,[12] and 47% for etanercept in Norway – a move that has prompted a price reduction on the original brand.[13] Whether these will prove exceptional or directional remains to be seen but they clearly raise new questions for originator manufacturers in their quest to remain leading and competitive.

Finding ways to add value

At the heart of the challenges is a constant: to date, the adoption of biosimilars has been checkered. Even in the case of the first MAb infliximab, uptake was rather variable by country.[14] As recently demonstrated in a comprehensive European analysis, their market share correlates poorly with the degree of price reduction.[15] This reflects a myriad of complex drivers, underscored by prevailing reservations and unmet needs. Together, these provide biologics manufacturers with opportunities for developing strategies to protect their brand position in the market. Based on our experience these can include efforts to:

Reassess price

Explore alternative pricing scenarios to understand the impact in new market situations and determine the optimal price level that can be offered in combination with value-added services, the acceptable price differential between the original brand and biosimilar versions, and the supporting factors that can justify this.

Harness brand power

Leverage brand equity, trust in the efficacy and safety data, and evidence from clinical practice to build the case for preferential use and forestall the adoption of biosimilars. Consider where and how differential value can best be demonstrated. For example, are there key situations where switching to a biosimilar would be unadvisable or even detrimental for patients?

Move the goal posts

Invest to renew the original brand with enhancements that will benefit physicians and patients and reinforce perceptions of it being the 'better product'. This may be an improved mode of administration, new formulation or more convenient dosing schedule, that potentially could demonstrate cost savings or strengthen compliance. An example can be seen in Roche's introduction of an injectable vs. iv formulation of Herceptin (trastuzumab) in 2013 before the drug lost exclusivity in Europe. Enabling much faster administration (2–5 minutes vs. 30–90 minutes previously), this offered both greater convenience for patients and time saving opportunities for healthcare professionals.[16]

Expand support services

Bolster existing or develop new wrap-around programs to strengthen the brand's value proposition and help create further differentiation. This will mean identifying and prioritizing current gaps in support services for patients, physicians, nurses and other stakeholders, understanding that needs will vary across markets and diseases and at different stages of the treatment journey.[17] Creating added value in this way with next-generation programs can help to reset expectations of support provision and increase the challenges for biosimilars to demonstrate market similarity.

Build on a heritage of established relationships

Strengthen engagement with key influencers of product use, including payers, providers and other stakeholders along the value chain. Connect to understand their perceptions and changing needs and identify innovative ways of working with them to help improve patient access and outcomes through appropriate and optimal use of biologics.

Keep innovating

Concentrate on innovation as the USP to keeping moving the market forward, focusing on adding value through scientific advancements and the development of next-generation biologics.

Market research for well-grounded strategies

In all cases, robust and targeted market research programs, leveraging a variety of methodologies, can serve to inform key issues and uncertainties and ensure that strategies are well-grounded in evidence. Careful preparation and a deep understanding of the many complex factors that impact the use of biosimilars will be key to ensuring the right answers to the right questions.

Sources

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